

Bryan W. Shaw, Ph.D., *Chairman*
Carlos Rubinstein, *Commissioner*
Toby Baker, *Commissioner*
Zak Covar, *Executive Director*



TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Protecting Texas by Reducing and Preventing Pollution

April 29, 2013

MR PHILIP J FLEISCHHACKER
VP OF STERILIZATION
AMERICAN CONTRACT SYSTEMS INC
4801 W 81ST ST STE 110
BLOOMINGTON MN 55437-1111

Re: Permit Application
Permit Number: 100925
Ethylene Oxide Sterilization
Houston, Harris County
Regulated Entity Number: RN106337850
Customer Reference Number: CN604035147

RECEIVED

JUL 01 2013

TCEQ
CENTRAL FILE ROOM

Dear Mr. Fleischhacker:

This is in response to your Form PI-1 (General Application for Air Preconstruction Permits and Amendments) concerning the above-referenced facility. Also, this will acknowledge that your application for the above-referenced permit is technically complete as of November 12, 2012.

A permit for your new facility is enclosed. The permit contains several general and special conditions that define the level of operation, a maximum allowable emission rates table (MAERT), and a permit face. We appreciate your careful review of the special conditions of the permit and assuring that all requirements are consistently met. In addition, the construction and operation of the facilities must be as represented in the application.

In addition, with this permitting action, Permit by Rule Registration Number 95413 has been voided. This information will be incorporated into the existing permit file.

This permit authorizes planned startup and shutdown emissions for only the sources identified on the MAERT. Maintenance activities were not represented in the application and are not authorized and will need to be authorized separately in the future.

This permit is effective as of the date of this letter and will be in effect for ten years from the date of approval.

You may file a **motion to overturn** with the Chief Clerk. A motion to overturn is a request for the commission to review the executive director's decision. Any motion must explain why the commission should review the executive director's decision. According to 30 TAC § 50.139, an action by the executive director is not affected by a motion to overturn filed under this section unless expressly ordered by the commission.

Mr. Philip J Fleischhacker
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Re: Permit Number: 100925

A motion to overturn must be received by the Chief Clerk within 23 days after the date of this letter. An original and 11 copies of a motion must be filed with the Chief Clerk in person, or by mail to the Chief Clerk's address on the attached mailing list. On the same day the motion is transmitted to the Chief Clerk, please provide copies to the applicant, the executive director's attorney, and the Public Interest Counsel at the addresses listed on the attached mailing list. If a motion to overturn is not acted on by the commission within 45 days after the date of this letter, then the motion shall be deemed overruled.

You may also request **judicial review** of the executive director's approval. According to Texas Health and Safety Code § 382.032, a person affected by the executive director's approval must file a petition appealing the executive director's approval in Travis County district court within 30 days after the **effective date of the approval**. Even if you request judicial review, you still must exhaust your administrative remedies, which includes filing a motion to overturn in accordance with the previous paragraphs.

Thank you for your cooperation and interest in air pollution control. If you need further information or have any questions, please contact Mr. Patrick Agumadu, P.E. at (512) 239-1271 or write to the Texas Commission on Environmental Quality, Office of Air, Air Permits Division, MC-163, P.O. Box 13087, Austin, Texas 78711-3087.

This action is taken under authority delegated by the Executive Director of the TCEQ.

Sincerely,



Michael Wilson, P.E., Director
Air Permits Division
Office of Air
Texas Commission on Environmental Quality

MPW/pna

Enclosure

cc: Mr. Larry A. Moon, P.E., Principal, Zephyr Environmental Corp, Austin
Bureau Chief Pollution Control & Prevention, Environmental Health Division, Houston
Department of Health and Human Services, Houston
Director, Harris County, Pollution Control Services, Pasadena
Air Section Manager, Region 12 - Houston

Project Number: 174169



TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
AIR QUALITY PERMIT



A Permit Is Hereby Issued To
American Contract Systems, Inc.
Authorizing the Construction and Operation of
Ethylene Oxide Sterilization
Located at **Houston, Harris County, Texas**
Latitude 29° 40' 47"N *Longitude* 95° 22' 33"W

Permit: 100925

Issuance Date : April 29, 2013

Renewal Date: April 29, 2023


For the Commission

1. **Facilities** covered by this permit shall be constructed and operated as specified in the application for the permit. All representations regarding construction plans and operation procedures contained in the permit application shall be conditions upon which the permit is issued. Variations from these representations shall be unlawful unless the permit holder first makes application to the Texas Commission on Environmental Quality (commission) Executive Director to amend this permit in that regard and such amendment is approved. [Title 30 Texas Administrative Code 116.116 (30 TAC 116.116)]
2. **Voiding of Permit.** A permit or permit amendment is automatically void if the holder fails to begin construction within 18 months of the date of issuance, discontinues construction for more than 18 months prior to completion, or fails to complete construction within a reasonable time. Upon request, the executive director may grant an 18-month extension. Before the extension is granted the permit may be subject to revision based on best available control technology, lowest achievable emission rate, and netting or offsets as applicable. One additional extension of up to 18 months may be granted if the permit holder demonstrates that emissions from the facility will comply with all rules and regulations of the commission, the intent of the Texas Clean Air Act (TCAA), including protection of the public's health and physical property; and (b)(1) the permit holder is a party to litigation not of the permit holder's initiation regarding the issuance of the permit; or (b)(2) the permit holder has spent, or committed to spend, at least 10 percent of the estimated total cost of the project up to a maximum of \$5 million. A permit holder granted an extension under subsection (b)(1) of this section may receive one subsequent extension if the permit holder meets the conditions of subsection (b)(2) of this section. [30 TAC 116.120(a), (b) and (c)]
3. **Construction Progress.** Start of construction, construction interruptions exceeding 45 days, and completion of construction shall be reported to the appropriate regional office of the commission not later than 15 working days after occurrence of the event. [30 TAC 116.115(b)(2)(A)]
4. **Start-up Notification.** The appropriate air program regional office shall be notified prior to the commencement of operations of the facilities authorized by the permit in such a manner that a representative of the commission may be present. The permit holder shall provide a separate notification for the commencement of operations for each unit of phased construction, which may involve a series of units commencing operations at different times. Prior to operation of the facilities authorized by the permit, the permit holder shall identify the source or sources of allowances to be utilized for compliance with Chapter 101, Subchapter H, Division 3 of this title (relating to Mass Emissions Cap and Trade Program). [30 TAC 116.115(b)(2)(B)(iii)]
5. **Sampling Requirements.** If sampling is required, the permit holder shall contact the commission's Office of Compliance and Enforcement prior to sampling to obtain the proper data forms and procedures. All sampling and testing procedures must be approved by the executive director and coordinated with the regional representatives of the commission. The permit holder is also responsible for providing sampling facilities and conducting the sampling operations or contracting with an independent sampling consultant. [30 TAC 116.115(b)(2)(C)]

6. **Equivalency of Methods.** The permit holder must demonstrate or otherwise justify the equivalency of emission control methods, sampling or other emission testing methods, and monitoring methods proposed as alternatives to methods indicated in the conditions of the permit. Alternative methods shall be applied for in writing and must be reviewed and approved by the executive director prior to their use in fulfilling any requirements of the permit. [30 TAC 116.115(b)(2)(D)]
7. **Recordkeeping.** The permit holder shall maintain a copy of the permit along with records containing the information and data sufficient to demonstrate compliance with the permit, including production records and operating hours; keep all required records in a file at the plant site. If, however, the facility normally operates unattended, records shall be maintained at the nearest staffed location within Texas specified in the application; make the records available at the request of personnel from the commission or any air pollution control program having jurisdiction; comply with any additional recordkeeping requirements specified in special conditions attached to the permit; and retain information in the file for at least two years following the date that the information or data is obtained. [30 TAC 116.115(b)(2)(E)]
8. **Maximum Allowable Emission Rates.** The total emissions of air contaminants from any of the sources of emissions must not exceed the values stated on the table attached to the permit entitled "Emission Sources--Maximum Allowable Emission Rates." [30 TAC 116.115(b)(2)(F)]
9. **Maintenance of Emission Control.** The permitted facilities shall not be operated unless all air pollution emission capture and abatement equipment is maintained in good working order and operating properly during normal facility operations. The permit holder shall provide notification for upsets and maintenance in accordance with 30 TAC 101.201, 101.211, and 101.221 of this title (relating to Emissions Event Reporting and Recordkeeping Requirements; Scheduled Maintenance, Startup, and Shutdown Reporting and Recordkeeping Requirements; and Operational Requirements). [30 TAC 116.115(b)(2)(G)]
10. **Compliance with Rules.** Acceptance of a permit by an applicant constitutes an acknowledgment and agreement that the permit holder will comply with all rules, regulations, and orders of the commission issued in conformity with the TCAA and the conditions precedent to the granting of the permit. If more than one state or federal rule or regulation or permit condition is applicable, the most stringent limit or condition shall govern and be the standard by which compliance shall be demonstrated. Acceptance includes consent to the entrance of commission employees and agents into the permitted premises at reasonable times to investigate conditions relating to the emission or concentration of air contaminants, including compliance with the permit. [30 TAC 116.115(b)(2)(H)]
11. **This** permit may not be transferred, assigned, or conveyed by the holder except as provided by rule. [30 TAC 116.110(e)]
12. **There** may be additional special conditions attached to a permit upon issuance or modification of the permit. Such conditions in a permit may be more restrictive than the requirements of Title 30 of the Texas Administrative Code. [30 TAC 116.115(c)]
13. **Emissions** from this facility must not cause or contribute to a condition of "air pollution" as defined in Texas Health and Safety Code (THSC) 382.003(3) or violate THSC 382.085. If the executive director determines that such a condition or violation occurs, the holder shall implement additional abatement measures as necessary to control or prevent the condition or violation.
14. **The** permit holder shall comply with all the requirements of this permit. Emissions that exceed the limits of this permit are not authorized and are violations of this permit.

Special Conditions

Permit Number 100925

Emission Limitations

1. This permit authorizes ethylene oxide (EtO) sterilization operations for a facility located at 7702 Parnell St., Houston, Harris County, Texas.

This permit authorizes emissions only from those points listed in the attached table entitled "Emission Sources - Maximum Allowable Emission Rates," and the facilities covered by this permit are authorized to emit subject to the emission rate limits on that table and other operating requirements specified in the special conditions.

In addition, this permit authorizes all emissions from planned startup and shutdown activities associated with facilities or groups of facilities that are authorized by this permit.

Federal Applicability

2. These facilities shall comply with all applicable requirements of the U.S. Environmental Protection Agency (EPA) regulations on National Emission Standards for Hazardous Air Pollutants for Source Categories in Title 40 Code of Federal Regulations Part 63 (40 CFR Part 63):
 - A. Subpart A, General Provisions.
 - B. Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities.
3. If any condition of this permit is more stringent than the applicable regulations in Special Condition No. 2, then for the purposes of complying with this permit, the permit shall govern and be the standard by which compliance shall be demonstrated.

Opacity/Visible Emission Limitations

4. Opacity of emissions from the Aeration Chambers Stacks (EPNs S-1 and/or S-2) shall not exceed zero percent, when adjusted for uncombined water vapor, averaged over a six-minute period, except for those periods described in Title 30 Texas Administrative Code (30 TAC) §§ 101.201 and 101.211. A visible emissions evaluation shall be performed on EPNs S-1 and S-2 during normal plant operations and the results recorded quarterly. The visible emissions observations shall be made at least 15 feet and no more than 0.25 miles from the emission point. If visible emissions are observed from the emission point, opacity shall be determined using the EPA 40 CFR Part 60, Appendix A, Test Method 9. Contributions from uncombined water vapor shall not be included in determining compliance with this condition.

Operational Limitations, Work Practices, and Plant Design

5. Sampling ports and platform(s) shall be incorporated into the design of the scrubbers venting to the Aeration Chambers Stacks (EPNs S-1 and/or S-2), as well as the stacks themselves, according to the specifications set forth in the attachment entitled "Chapter 2, Stack Sampling Facilities" of the Texas Commission on Environmental Quality (TCEQ) Sampling Procedures Manual. Alternate sampling facility designs must be submitted for approval to the TCEQ Regional Director.
6. The Safe Cell dry bed scrubbers venting to the Aeration Chambers Stacks (Emission Point Nos. [EPNs] S-1 and/or S-2) shall operate with no less than 99.0 percent removal efficiency for EtO on an hourly average, and a per stack exit concentration of no more than 15 parts per million, by volume (ppmv), at a per stack exit rate of no more than 1563 standard cubic feet per minute (scfm).
7. EtO usage shall be limited to a maximum annual rate of 3,000 pounds.
8. Sterilization gas usage shall be 100 percent EtO. Use of any other sterilization gas, or mixtures of sterilant gas and other gases, shall require prior approval from the Executive Director of the TCEQ.
9. Process gases shall be stored in such a manner as to prevent damage to the storage container and release of uncontrolled emissions. A maximum of 240 pounds of EtO will be kept on-site at any time.
10. All air pollution abatement equipment shall be properly maintained and operated during the operation of these facilities. Cleaning and maintenance of the abatement equipment shall be performed as recommended by the manufacturer as necessary so that the equipment efficiency can be adequately maintained.
11. All hooding, duct, and collection systems shall be effective in capturing emissions from this equipment and in minimizing fugitive emissions from the building. The hooding and duct system shall be maintained free of holes, cracks, and other conditions that would reduce the collection efficiency of the emission capture system.
12. The holder of this permit shall physically identify and mark in a conspicuous location, all equipment that has the potential of emitting air contaminants. This shall include (but is not limited to) the facility identification number as submitted to the Emissions Inventory Section of the TCEQ and the EPN as listed on the maximum allowable emission rates table (MAERT).
13. All aeration chambers may operate continuously as long as they vent EtO emissions to their designated Safe Cell Systems. The Safe Cell Systems may operate continuously.
14. Any leak in the EtO injection equipment housing shall automatically lock-out the unit until the issue is resolved.

15. The stack height of the Aeration Chambers Stacks (EPNs S-1 and/or S-2) shall be no less than 43 feet above the ground.

Initial Demonstration of Compliance

16. The permit holder shall perform stack sampling and other testing as required to establish the actual pattern and quantities of air contaminants being emitted into the atmosphere from the Safe Cell dry bed scrubbers venting to the Aeration Chambers Stacks (EPNs S-1 and/or S-2) to demonstrate compliance with the MAERT and the requirements of Special Condition No. 6. The permit holder is responsible for providing sampling and testing facilities and conducting the sampling and testing operations at his expense. Sampling shall be conducted in accordance with the appropriate procedures of the TCEQ Sampling Procedures Manual and the EPA Reference Methods.
- A. The appropriate TCEQ Regional Office shall be notified not less than 45 days prior to sampling. The notice shall include:
- (1) Proposed date for pretest meeting.
 - (2) Date sampling will occur.
 - (3) Name of firm conducting sampling.
 - (4) Type of sampling equipment to be used.
 - (5) Method or procedure to be used in sampling.
 - (6) Description of any proposed deviation from the sampling procedures specified in this permit or TCEQ/EPA sampling procedures.
 - (7) Procedure/parameters to be used to determine worst case emissions, such as the total number and size of bags being aerated, the time since the bags were charged with EtO, and the number of aeration chambers running that are attached to the Safe Cell dry bed scrubber being tested, during the sampling period.

The purpose of the pretest meeting is to review the necessary sampling and testing procedures, to provide the proper data forms for recording pertinent data, and to review the format procedures for the test reports. The TCEQ Regional Director must approve any deviation from specified sampling procedures.

- A. Air contaminants emitted from EPNs S-1 and/or S-2 to be tested for include (but are not limited to) EtO.
- B. Sampling shall occur within 60 days after achieving the maximum operating rate, but no later than 180 days after initial start-up of the facilities, and at such other times as may be required by the TCEQ Executive Director. Requests for additional time to perform sampling shall be submitted to the appropriate regional office.

- C. The facility being sampled shall operate under such conditions as have been identified and agreed upon within the pretest meeting that are expected to cause maximum emissions for each air contaminant to be tested during stack emission testing. These conditions/parameters and any other primary operating parameters that affect the emission rate shall be monitored and recorded during the stack test. Any additional parameters shall be determined at the pretest meeting and shall be stated in the sampling report. Permit conditions and parameter limits may be waived during stack testing performed under this condition if the proposed condition/parameter range is identified in the test notice specified in paragraph A and accepted by the TCEQ Regional Office. Permit allowable emissions and emission control requirements are not waived and still apply during stack testing periods.

During subsequent operations, if the total number and size of bags being aerated, the time since the bags were charged with EtO, the number of aeration chambers running that are attached to a given scrubber, or any other process conditions is such as to produce emissions that are greater than that recorded during the test period, stack sampling shall be performed at the new operating conditions within 120 days. This sampling may be waived by the TCEQ Air Section Manager for the region.

- D. Copies of the final sampling report shall be forwarded to the offices below within 60 days after sampling is completed. Sampling reports shall comply with the attached provisions entitled "Chapter 14, Contents of Sampling Reports" of the TCEQ Sampling Procedures Manual. The reports shall be distributed as follows:

One set of copies to the appropriate TCEQ Regional Office.

One set of copies to each local air pollution control program.

Continuous Demonstration of Compliance

17. The EtO concentration of the exhaust from the Safe Cell control system (aeration chamber exhaust) shall be periodically monitored and recorded according to the following schedule:

When the concentration in the exhaust is below 0.5 ppm, samples of the exhaust will be collected and analyzed once per month.

When the exhaust concentration is between 0.5 ppm and 0.75 ppm, samples will be collected and analyzed every two weeks.

When the concentration exceeds 0.75 ppm, the permit holder will sample and analyze the exhaust concentration each week.

Recordkeeping Requirements

18. Records (electronically or in hard copy) shall be maintained at this facility site and made available at the request of personnel from the TCEQ or any other air pollution control program having jurisdiction to demonstrate compliance with permit limitations. These records shall be totaled for each calendar month, retained for a rolling 24-month period, and include the following:
- A. Quarterly visible emission evaluations.
 - B. The EtO injection equipment shall maintain electronic logs of each EtO injection, including the quantity of EtO used.
 - C. All sterilization gas usage in pounds on a daily basis shall be compiled from equipment maintained electronic logs of each ethylene oxide injection, including the quantity of ethylene oxide used.
 - D. Ethylene oxide purchased and used each year shall be maintained, either electronically or on paper, on a rolling 12-month record.
 - E. Sample results of the Safe Cell system exhaust concentration as required by Special Condition Nos. 16 and 17.
 - F. Records of EtO inventory showing compliance with Special Condition No. 9.
 - G. Any time the EtO sensors (including, but not limited to the continuous monitoring for ethylene oxide leaks within the injection equipment housing) are activated and the reason for the event and the correction action taken.

Dated: April 29, 2013

Emission Sources - Maximum Allowable Emission Rates

Permit Number 100925

This table lists the maximum allowable emission rates and all sources of air contaminants on the applicant's property covered by this permit. The emission rates shown are those derived from information submitted as part of the application for permit and are the maximum rates allowed for these facilities, sources, and related activities. Any proposed increase in emission rates may require an application for a modification of the facilities covered by this permit.

Air Contaminants Data

Emission Point No. (1)	Source Name (2)	Air Contaminant Name (3)	Emission Rates (5)	
			lbs/hour	TPY (4)
S-1	Aeration Chambers Stack No. 1	EtO	0.16	0.008
S-2	Aeration Chambers Stack No. 2	EtO	0.16	0.008

- (1) Emission point identification - either specific equipment designation or emission point number from plot plan.
- (2) Specific point source name. For fugitive sources, use area name or fugitive source name.
- (3) EtO - ethylene oxide.
- (4) Compliance with annual emission limits (tons per year) is based on a 12 month rolling period.
- (5) Planned startup and shutdown emissions are included. Maintenance activities are not authorized by this permit.

Date: April 29, 2013

Construction Permit Source Analysis & Technical Review

Company	American Contract Systems, Inc.	Permit Number	100925
City	Houston	Project Number	174169
County	Harris	Account Number	N/A
Project Type	Initial	Regulated Entity Number	RN106337850
Project Reviewer	Mr. Patrick Agumadu, P.E.	Customer Reference Number	CN604035147
Site Name	Sterile Processing Facility		

Project Overview

American Contract Systems (ACS) is requesting this permit to authorize the additional use of ethylene oxide (EtO) in the existing sterile processing plant beyond the 1,000 pounds per annual usage limit in the Permit By Rule (PBR) 106.417, Registration No. 95413.

The sterile processing plant located in Houston, Harris County, Texas is authorized under PBR Reg. No. 95413. The plant is designed to prepare and sterilize "packs" of medical equipment and supplies primarily for use in the Methodist Hospital system, but also for customers outside the Methodist Hospital system. The sterilizer and packaging equipment is owned and operated by American Contract Systems. The Methodist Hospital owns the warehouse which houses the sterilizer and the property upon which the warehouse sits. The customer base has grown such that it is necessary to obtain authorization to use ethylene oxide in excess of the 1,000 pound annual usage limit in PBR 106.417.

Since the entire facility previously under PBR is being consolidated, the Best Available Control Technology (BACT) being applied meets the requirements for the BACT for the PBR.

There is no proposed new equipment or modification of existing equipment in this project.

The consultant indicated that there are no maintenance, startup, and shutdown activities associated with this facility.

Emission Summary

Air Contaminant	Current Allowable Emission Rates (tpy)*	Proposed Allowable Emission Rates (tpy)	Change in Allowable Emission Rates (tpy)
HAP (ethylene oxide)	0.50	0.016	-0.48
VOC	0.50	0.016	-0.48

* Current authorization from PBR No. 95413

Compliance History Evaluation - 30 TAC Chapter 60 Rules

A compliance history report was reviewed on:	10/01/2012
Compliance period:	09/01/2007 – 08/31/2012
Site rating & classification:	3.01 (Unclassified)
Company rating & classification:	Not Available/Applicable
If the rating is 50<RATING<55, what was the outcome, if any, based on the findings in the formal report:	N/A
Has the permit changed on the basis of the compliance history or rating?	No

Public Notice Information - 30 TAC Chapter 39 Rules

Rule Citation	Requirement	Due Date
39.403	Date Application Received:	February 3, 2012
	Date Administratively Complete:	February 16, 2012

Construction Permit Source Analysis & Technical Review

Permit No. 100925
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Regulated Entity No. RN106337850

Rule Citation	Requirement	
	Small Business Source?	No
	Date Leg Letters mailed:	February 16, 2012
39.603	Date Published:	03/08/2012
	Publication Name:	Houston Chronicle
	Pollutants:	EtO
	Date Affidavits/Copies Received:	03/23/2012
	Is bilingual notice required?	Yes
	Language:	Spanish
	Date Published:	03/11/2012
	Publication Name:	Houston Chronicle DbA LaVoz
	Date Affidavits/Copies Received:	03/23/2012
	Date Certification of Sign Posting / Application Availability Received:	04/24/2012
39.604	Public Comments Received?	No
	Hearing Requested?	No
	Meeting Request?	No
	Is 2nd Public Notice required?	Yes
39.419	Date 2nd Public Notice/Preliminary Decision Letter Mailed:	01/15/2013
39.603	Date Published:	02/20/2013
	Publication Name:	Houston Chronicle
	Pollutants:	EtO
	Date Affidavits/Copies Received:	02/26/2013
	Is bilingual notice required?	Yes
	Language:	Spanish
	Date Published:	02/20/2013
	Publication Name:	Houston Chronicle DbA LaVoz
	Date Affidavits/Copies Received:	02/26/2013
	Date Certification of Sign Posting / Application Availability Received:	03/28/2013
	Public Comments Received?	No
	Meeting Request?	No
	Hearing Request?	No

Construction Permit & Amendment Requirements - 30 TAC Chapter 116 Rules

Rule Citation	Requirement	
116.111(a)(2)(G)	Is the facility expected to perform as represented in the application?	Yes
116.111(a)(2)(A)(i)	Are emissions from this facility expected to comply with all TCEQ air quality Rules & Regulations, and the intent of the Texas Clean Air Act?	Yes

Construction Permit Source Analysis & Technical Review

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Regulated Entity No. RN106337850

Rule Citation	Requirement	
116.111(a)(2)(B)	Emissions will be measured using the following method: Emissions will be measured using the following method: (a) The equipment will maintain electronic logs of each ethylene oxide injection, including the quantity of ethylene oxide used. Ethylene oxide purchased and used each year will be maintained, either electronically or on paper, on a rolling 12-month record. Emissions are thus calculated based upon the represented removal effectiveness of the scrubbers. (b) Stack Testing to verify performance of the scrubbers	
	Comments on emission verification:	N/A
116.111(a)(2)(D)	Subject to NSPS? No – facility is not subject to any of the requirements of 40 CFR 60	
116.111(a)(2)(E)	Subject to NESHAP? No – facility does not emit any air contaminant regulated under 40 CFR 61	
116.111(a)(2)(F)	Subject to NESHAP (MACT) for source categories? Subparts A & O for Ethylene Oxide Emissions for Sterilization Facilities	Yes
116.111(a)(2)(H)	Is nonattainment review required? No - while Harris County is non-attainment (severe), this project/permit is well below the 25 tpy VOC threshold	
116.111(a)(2)(I)	Is PSD applicable? No – site not a named source and does not emit 250 tpy of EtO	
116.111(a)(2)(L)	Is Mass Emissions Cap and Trade applicable to the new or modified facilities? If yes, did the proposed facility, group of facilities, or account obtain allowances to operate:	No N/A
116.140 - 141	Permit Fee: \$900.00 (R217948) Fee certification:	Yes

Title V Applicability - 30 TAC Chapter 122 Rules

Rule Citation	Requirement	
122.10(13)(A)	Is the site a major source under FCAA Section 112(b)?	No- emits less than 1 tpy of HAP
	Does the site emit 10 tons or more of any single HAP?	No
	Does the site emit 25 tons or more of a combination?	No
122.10(13)(C)	Does the site emit 100 tons or more of any air pollutant?	No
122.10(13)(D)	Is the site a non-attainment major source?	No
122.602	Periodic Monitoring (PM) applicability: The equipment will maintain electronic logs of each ethylene oxide injection, including the quantity of ethylene oxide used. Ethylene oxide purchased and used each year will be maintained, either electronically or on paper, on a rolling 12-month record.	
122.604	Compliance Assurance Monitoring (CAM) applicability: Since the site is not a major source for HAPs, or any other pollutants, the site is not subject to CAM. However, the continuous monitoring for ethylene oxide leaks within the injection equipment housing is a form of CAM.	

Construction Permit Source Analysis & Technical Review

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Regulated Entity No. RN106337850

Request for Comments

Received From	Program/Area Name	Reviewed By	Comments
Region:	12	Rebecca P. Miller	An incorrect cross reference, "TCEQ Regional Director" doesn't specify which region, the new Chapter 14 requires one hard copy and two CDs to be submitted to the region, and two sub-conditions of SC 18 appear to be the same requirement.
City:	Houston	Isaac H. DeSouza	No comments
Comment resolution and/or unresolved issues:			Corrected the cross reference; changed the use of "One copy", in sub-condition E of the Stack Sampling boilerplate, to "One set of copies"; and eliminated the duplicate sub-condition of SC 18.

Process/Project Description

The sterile processing plant is tasked with preparing and sterilizing "packs/bags" of medical equipment and supplies. The equipment and supplies are retrieved from storage, organized within the bag, and then charged with a pre-programmed amount of ethylene oxide. Each bag is tested for integrity via a vacuum check at the time it is filled. If the bag fails the vacuum test, it is discarded. In addition, any leak in the injection equipment housing automatically locks-out the unit until the issue is resolved.

The charged packs are then placed in aeration cabinets for several days. Some ethylene oxide is reacted in the pack while the remaining ethylene oxide diffuses through the permeable package wall into the cabinet. The cabinet is under negative pressure and the ethylene oxide exiting the pack will be pulled through a vent system to one of two dry bed scrubbers. There are six aeration chambers, with three chambers vented to each scrubber.

The dry bed scrubbers are at least 99.0% effective in removing the ethylene oxide from the effluent stream, and will exhaust vertically from the building (via Emission Point Nos. S-1 and S-2). After the designated aeration period, the packs are removed from the cabinet and shipped to their destination.

Ethylene oxide is brought onsite in pressurized cylinders. A maximum of 240 pounds of ethylene oxide will be kept onsite at any time. Disaster review is not required since the maximum amount of Ethylene Oxide kept on site does not exceed the threshold amount of 10,000 pounds.

Pollution Prevention, Sources, Controls and BACT- [30 TAC 116.111(a)(2)(C)]

Emissions of ethylene oxide are controlled by dry bed scrubbers on each stack which provide a 99.0% control efficiency. This meets BACT for Ethylene Oxide Sterilization Units, and MACT 40 CFR 63, Subpart O. Since the entire facility previously under PBR is being consolidated, the installation of dry bed scrubbers meets the requirements for the BACT for the PBR.

Construction Permit
Source Analysis & Technical Review

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Regulated Entity No. RN106337850

Impacts Evaluation - 30 TAC 116.111(a)(2)(J)


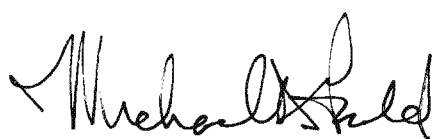
Was modeling conducted?	Yes	Type of Modeling:	SCREEN ₃
Will GLC of any air contaminant cause violation of NAAQS?			No
Is this a sensitive location with respect to nuisance?			Low to moderate
[§116.111(a)(2)(A)(ii)] Is the site within 3000 feet of any school?			No
Additional site/land use information: The site is adjacent to off-site commercial property			

Summary of Modeling Results

At the emission rates authorized by PBR registration No. 95413 the short term (ST) maximum ground level concentration (GLC_{max}) of ethylene oxide (EtO) is 5.2 µg/m³, compared to the ST ESL of 20 µg/m³, and the annual or long term (LT) GLC_{max} is 0.4 µg/m³, compared to the LT ESL of 2 µg/m³. At the proposed emission rates the ST GLC_{max} of EtO increases to 14.6 µg/m³, compared to the ST ESL of 20 µg/m³, and the LT GLC_{max} is reduced to 0.01 µg/m³, compared to the LT ESL of 2 µg/m³. Based on this information, it is believed that the emissions from this facility will not cause any adverse impact on health and property.

Permit Concurrence and Related Authorization Actions

Is the applicant in agreement with special conditions?	Yes
Company representative(s):	Philip Fleischhacker
Contacted Via:	email
Date of contact:	01/09/2013
Other permit(s) or permits by rule affected by this action:	Previous authorization: PBR No. 95413
List permit and/or PBR number(s) and actions required or taken:	Void PBR No. 95413

			
P. N. Aguinaldo	4/18/2013	Michael D. Feld	04/18/2013
Project Reviewer	Date	Team Leader/Section Manager/Backup	Date